DRAFT GUIDANCE

Applying for Other Uses of Phosphogypsum: Submitting a Complete Petition 40 CFR 61.206

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Prepared for:

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1.0 Introduction

1.1 What is the purpose of this document?

The purpose of this document is to provide information on how to prepare a complete petition to the U.S. EPA for the distribution and use of phosphogypsum for "other purposes" that is consistent with the requirements of the Subpart R rule for radon emissions from phosphogypsum stacks. (See Appendix A for the complete text of the rule.) This document includes guidance on petition procedures, content, analysis, and the review and approval process. It is designed to help you submit a complete petition for approval of other uses of phosphogypsum. We have included a checklist in Appendix B to assist you in submitting a complete petition.

What is Subpart R? EPA has developed National Emissions Standards for Hazardous Air Pollutants (NESHAP), titled "Subpart R, National Emission Standards for Radon Emissions from Phosphogypsum Stacks." The rule limits radon emissions from phosphogypsum stacks and requires disposal of phosphogypsum in stacks or piles, with exceptions for agricultural and research uses and other uses on a case-by-case basis.

1.2 Does this guidance replace the regulation?

No. This document **does not** replace or change the final rule and covers only requirements published on or before **09/30/04**. Contact us to make sure you have the latest version of the subpart R rule, which is located in part 61 of title 40, chapter I of the Code of Federal Regulations ("40 CFR 61").

Subpart R was most recently amended on February 3, 1999. You can find a copy of the *Federal Register* notice (64 FR 5574, titled: "National Emission Standards for Radon Emissions from Phosphogypsum Stacks") through the Office of Federal Register main page at: http://www.gpoaccess.gov/fr/index.html. You can see the most up-to-date version of the rule at http://www.gpoaccess.gov/cfr/index.html. We've also included the complete text of subpart R in Appendix A.

1.3 Where can I get more information?

This document compiles and supplements a wealth of information that is available on the EPA radiation website. See the website at http://www.epa.gov/radiation/neshaps/subpartr/index.html for additional information.

1.4 Who do I contact if I have questions about the regulation or petition process?

You may contact our staff in the Office of Radiation and Indoor Air using the following information:.

Phone	(202) 343-9290
FAX	(202) 343-2304
US Mail	Office of Radiation and Indoor Air U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Mail Code 6608J Washington, DC 20460-0001
E-Mail	radiation.questions@epa.gov

Figure 1. Phosphogypsum Stacks

2.0 Petition Process

2.1 How do I start the petition process?

If you have a potential use for phosphogypsum, you may apply for an exemption from the existing use and disposal requirements. You may apply for other use approval by following the specific steps listed in the regulation. The two key elements in any proposal for alternative use are:

- A detailed description of your idea for using phosphogypsum and how you plan to implement your idea.
- A risk analysis to demonstrate that introduction of this material into the environment will not result in greater risks to the public or the environment than leaving the phosphogypsum in the stacks.

> Phosphogypsum stacks are a less than ideal management alternative, but they still represent the best option we have identified to date for the majority of material generated.

Note that you must have EPA approval before you do anything with phosphogypsum other than those uses already allowed under subpart R. You may not proceed with any project on a "petition pending" basis.

We encourage you to contact us early in the development process. Even if you're just thinking about an idea, wondering if it's been done before, or even feasible, we encourage you to contact us. It may save you a lot of time and trouble. While we do not fund efforts to seek alternatives uses, there are several organizations that may provide funding and/or other assistance. These include:

- Phosphate mining and processing companies.
- State government or the municipal agencies responsible for managing phosphate operations. For example, Florida has created a group devoted to finding solutions to the problem and has funded its research and development.
- Local and national environmental groups.

Contact us if you need more information on potential partners. We will share any information we have about organizations or companies that may provide funding.

This guidance document provides a suggested format for your petition. However, each case is different and you should feel free to use any well-organized

> If possible, submit both a hard copy and an electronic copy of the entire petition. If this is not possible, these steps will help us review your petition:
>
> - Number the pages in the body of the petition as well as the pages in any appendices.
> - Do not permanently bind your petition, so that we can make additional copies for the review process.
> - Submit one original (marked as such) and two copies.

format. Fancy presentations aren't required either. Our review is made on technical merit rather than presentation. However, we prefer simple, straightforward petitions.

2.2 What should I include in the description of my potential use and how it's implemented?

Your petition must provide the information requested in 40 CFR 61.206, "Distribution and use of phosphogypsum for other purposes." We are looking for specific pieces of information about the applicant, whether you are applying for yourself or another person. The information required includes the following:

- The name and address of the person(s) making the request.
- A description of the proposed use, including any handling and processing that the phosphogypsum will undergo. Be specific for each phase or step. Remember we may not be familiar with the technology.
- The location of each facility, including suite and/or building number, street, city, county, state, and zip code, where any use, handling, or processing of the phosphogypsum will take place. If the mailing address is different, provide it too.
- The quantity of phosphogypsum to be used by each facility. Remember, each petition is for a specific amount, which may not be exceeded. If you aren't sure, estimate on the high side. This will save you from having to call us later for approval of a larger amount.
- The average concentration of radium-226 in the phosphogypsum to be used. This information may be available from the owner of the stack. The sampling must have been done within the past 12 months.
- A description of any measures which will be taken to prevent the uncontrolled release of phosphogypsum into the environment. Please be specific when you provide this information.
- An estimate of the maximum individual risk and incidence associated with the proposed use, including the ultimate disposition of the phosphogypsum or any product in which the phosphogypsum is incorporated.
- How the applicant will dispose of any unused phosphogypsum.

Each request must be signed and dated by a corporate officer or public official in charge of the facility.

Section 3.0 contains more information on the project description elements of the petition.

2.3 What must I do to show that the potential use won't be any more hazardous than storing phosphogypsum in stacks?

Your petition must include the results of a risk assessment demonstrating that the proposed other use will not cause a threat to the public or environment greater than if the phosphogypsum were left in the stack. As part of the NESHAP rulemaking process, we conducted an assessment of the maximum individual lifetime risk of fatal cancer from radon emissions from stacks. This risk was estimated to be less than three in ten thousand to the maximally exposed individual. This risk threshold is consistent with the determination of a "safe" level first announced in the NESHAPs for certain benzene source categories (54 FR 38044, September 13, 1989). Based on our analysis, we also determined that this level provides an ample margin of safety, considering the cost, scientific uncertainty, and technological feasibility of control technologies needed to further reduce the radon emissions from stacks. Therefore, your proposed alternative use petition must demonstrate that the alternative use does not exceed a three in 10 thousand maximum individual risk level.

Sections 4.0 and 5.0 on Risk Assessment and Risk Assessment Models have more detailed information on how to complete the risk assessment portion of your petition.

2.4. What steps will EPA take to review and approve my petition?

As suggested above, we urge you to contact us early in the development of your petition. Once you submit a petition, we will assign an Office of Air and Radiation (OAR) staff person to your petition. This person will work with you to ensure your petition is processed as quickly as possible and will keep you up-to-date on our progress. We seek to review your petition and give you a determination in a timely manner.

Our first step will be to assess your petition for completeness. We cannot finalize or review incomplete petitions or petitions that contain inaccurate or questionable data or analyses. We will look for the following three elements in our completeness determination:

- A demonstration that the potential radiological risk from the alternative use is at least as protective as placement of phosphogypsum in a stack or mine, consistent with regulations.
- A description of the proposed monitoring scheme covering both radiological and non-radiological parameters with sufficient detail to demonstrate that the project does not adversely affect the environment and that the project is an effective and appropriately identified small-scale study (or other application) or a justification for why monitoring is not needed.
- Some discussion and documentation that the description of the project lies within generally accepted methodologies for such research, that the effectiveness and

benefit of such research is adequately documented, and that the proposed use is legitimate (i.e., not considered "disposal").

We have included an example completeness checklist in Appendix B to help you develop your petition. During this phase, we would expect to work closely with you to identify any information gaps and address questions we may have regarding your petition. If we still find that the petition is incomplete, we will document in a letter to you any deficiencies we find and offer suggestions for how you might remedy them. At that point, you will be welcome to resubmit your petition with additional material.

Once we determine you have a complete petition, we will notify you that we are starting the technical review phase of your petition. Once that review is complete, we will issue a notice of pending approval or a notice of disapproval signed by the OAR Assistant Administrator. If the petition is to be approved, we will ask you to submit a copy of the complete petition to the public library closest to the site of the intended alternative use and another to the public library closest to the phosphogypsum stack. We will publish a notice of our pending approval in the local newspapers near the site and stack informing the public of our pending approval, the location of the libraries where the petition is available for public review, and notice that we will approve the petition in 30 days unless significant adverse comments are received. We will also directly notify other stakeholders of our pending approval.

Upon receipt of public comments, we will review them for their significance and determine if they contain information that would lead to a concern for human health or environmental impacts not previously considered in the risk analysis, some other reason to reconsider our decision to approve, or the potential to revise the finding that the alternative use is at least as protective as leaving the phosphogypsum in the stack. If we determine that there are adverse comments, we will advise you of the comments and give you an opportunity to amend your analysis or proposed use, or take other steps to address the public concerns. If we determine that the amended petition is approvable, we will notify the local newspapers that a "response to comments" document is available on our website, and issue the approval.

Consistent with 40 CFR 61.106(e), if we decide to grant a request that approves distribution and/or use of phosphogypsum for a specified purpose, we may decide to impose additional terms or conditions governing such distribution or use. In some cases, we may require you to take special precautions. For example, if you were proposing to use phosphogypsum in a way that would bring it into contact with the surface of the ground, such as using it for a road base, we might require you to establish a groundwater monitoring program. See section 6.0 of this guidance document for more discussion of post-approval requirements.

Since each idea is different, the length of time we need to review each proposal is different. You can expect the length of the review period to depend on the scope of the project, its level of complexity, and the quality of your petition. If your petition is simple,

straightforward, and complete, we may be able to review and approve it in a matter of months. If it is complex, we will probably need more time and may need to consult with experts outside the Agency, which can extend the review period. To the extent your proposal is similar to other proposals we have approved, we anticipate there may be some opportunity for streamlining the process.

Unless there is material, such as details about a proprietary process, that you have marked confidential business information (CBI), we will make the entire petition available to the public. In some circumstances, we will also provide copies of your petition to local and state officials for their comments. Therefore, if you believe that disclosure of information in your petition would reveal a trade secret or is otherwise considered CBI, you should clearly identify such information in your submittal. Any information subsequently determined to constitute CBI will be protected under 18 U.S.C. 1905. If no claim of confidentiality accompanies the information when it is received by us, it may be made available to the public by us without further notice (40 CFR 2.203(a)(2)). Note that emissions data are exempt from claims of confidentiality, and any emissions data you provide may be made available to the public. Contact us if you have any concerns about how we will handle CBI.

3.0 Project Description

Based on our experience with petitions we have received to date, we expect that most petitions for new uses will start with a small-scale (field) study designed to validate the proposed use. Subsequent to successful completion of a small-scale study, we would expect you to submit a follow-on petition for more wide-spread use of the proposed process or material. Therefore, this document emphasizes the important role that a properly designed small-scale study would play in the process of considering a request to use or distribute phosphogypsum for other purposes. There is no requirement for you to pursue a small-scale study. However, documentation of the proposed use through a small-scale study can greatly advance your ability to make the needed showing that your proposed use meets our approval criteria.

Several possible "other uses" of phosphogypsum have been explored over the years. These include:

- Landfill daily cover material
- Road base material
- Marine environment stabilization (oyster culch and riprap applications)
- Grassland fertilizer
- Glass-ceramic tiles
- Cement, wallboard, and other building materials.

Of these uses, the most recent interest has been in the area of landfill daily cover material. Because land applications are a common type of petition, this guidance will focus on the design of projects to address land-based proposals. We also expect that this guidance will provide a general template for other types of application. Note, however, that other applications may involve additional concerns or requirements that must be addressed. For example, a project that would affect the marine environment may require your compliance with the Marine Protection, Research, and Sanctuaries Act (MPRSA, also known as the Ocean Dumping Act), which prohibits the dumping of material into the ocean that would unreasonably degrade or endanger human health or the marine environment. Ocean dumping cannot occur unless a permit is issued under the MPRSA.

The rest of this section will discuss the key elements that comprise a good project description in addition to the listed requirements in 40 CFR 61.206.

3.1 How do I describe the proposed small-scale study?

A small-scale study is the intermediate step between laboratory testing and full-scale implementation of the alternative use. Because of its smaller size, both costs and potential risks are lower in a small-scale study than in the full-scale implementation of the alternative use. The small-scale study is designed to simulate alternative use conditions as much as possible. At a

minimum, a small-scale study will consist of two components – a field test demonstrating how the proposed alternative would function and a control test to generate baseline conditions. Good study design ensures that activities in the field test component will be identical to activities in the control test component. In other words, the field test and control test will be subject to the same conditions at the same time.

We encourage you to describe the proposed use as completely as possible. Your petition should include a detailed description of the small-scale study that includes engineering drawings that clearly show the design of the field test and control test. Where needed, these should be in both plan-view and in cross-section, with detail drawings as appropriate. For example, in a landfill application, you should provide detailed information on the design of the geomembrane layer (seam specifics), the hydraulic conductivity of the clay layer, distances to monitoring wells, leachate circulation system design (if used), test cell sumps, etc. Please contact us for a more detailed description of what would be needed in your specific project.

3.2 How do I characterize the phosphogypsum waste?

As part of your petition, you must report the average concentration of radium-226 in the phosphogypsum you propose to use. This information should be available from the owner or operator of the phosphogypsum stack. 40 CFR 61.207 describes the procedures that the owner or operator must follow in determining the concentration. Then, if your petition is approved, you must meet the 40 CFR 61.208 certification requirements to document the concentration that is determined. See section 6.4 for more information on the certification requirements.

In addition to information on the average radium concentration of the phosphogypsum you will be using, you also must provide information on the other characteristics of the waste. For example, it may be important to analyze the waste for other toxic or hazardous constituents in order to understand the basic nature of the material, particularly if there is a breach in containment. Mobility of different constituents varies and can be an early indicator of a potential leak in the system. In that event, constituents other than radionuclides may be the first to breach the unit and an analysis of the waste would provide the information to answer that question.

Many leach tests are available to assess the mobility of various constituents and to assess contaminated soil scenarios. Some tests may be appropriate in specific situations, e.g., EPA Method 1311, the Toxicity Characteristic Leaching Procedure (TCLP), models leaching in a municipal landfill environment. The EPA Method 1312, the Synthetic Precipitation Leaching Procedure (SPLP), is designed to determine the mobility of both organic and inorganic analytes present in liquids, soils, and wastes. The SPLP was developed to model an acid rain leaching environment and is generally appropriate for a contaminated soil scenario. Like most leach tests, the SPLP may not be appropriate for all situations (e.g., soils contaminated with oily constituents may not yield suitable results). Therefore, one or more leach tests may be needed to adequately characterize the phosphogypsum waste proposed for your petition.

3.3 How does the small-scale study measure success?

The criteria used in determining success or failure of the tests needs to be explicit in the petition. In the landfill example, one of the proposed benefits in this application method is the enhanced biodegradation of the solid waste landfill material. The petition should explain the factors that will be used to measure performance (e.g,, settlement rate or time/distance of settlement) compared to the control test.

3.4 How does the small-scale study limit or control possible undesirable results?

This part of the petition should address quality control/quality assurance (QA/QC) measures you will take to ensure that the small-scale study generates the anticipated results and does not generate unexpected and/or undesirable results. In a landfill application, information on the type of liner, how it is installed, and steps taken to prevent leaks should be presented. You should develop a QA/QC plan that addresses leak prevention potential for liquids, solids, and gases. For example, hydrogen sulfide (H_2S) is a common and very reactive landfill gas. Will you take measurements to estimate the potential for its generation? How will you monitor for the generation during the experiment? Will there be odor concerns from the emissions of H_2S and how will you manage them?

3.5 How do I monitor potential exposures?

Your petition should address all relevant exposure pathways, which will include air as well as groundwater, ingestion, or others depending on the proposed use. You will be expected to provide background documentation describing baseline exposure levels, anticipated exposure levels, and how you will monitor exposure.

The air pathway should always be included as a potential pathway of exposure for phosphogypsum. Movement of the materials from the stack to the area of alternative use can result in particle and contaminated soil resuspension while diffuse radiation exposure from the stack can occur at any time. Ambient air monitors can be used to estimate the potential exposure to the general public through careful placement along the boundaries of the stack site and the alternative use site. Place the monitors where maximum air concentrations of contaminants are expected. Worker air pathway exposure can be estimated through the use of personal monitoring devices. Personal monitors such as radiation badges or portable particulate samplers are worn by the workers and provide a more precise estimate of exposure than the ambient monitors since the workers move around the site.

In land applications, the groundwater pathway must be considered a potential route of exposure in addition to the air pathway. Your project description must explain how you will monitor the surrounding area to predict the impacts resulting from the small-scale study and to

determine if there are leaks in the system. You should submit a groundwater monitoring plan that includes the following elements:

- Procedures and techniques for the following:
  - Sample collection
  - Sample preservation and shipment
  - Analytical procedures
  - Constituents to be analyzed
  - Chain of custody control
  - How you will determine if there has been a migration of constituents out of the test site.
- An engineering drawing that shows the location of monitoring wells and a schematic showing how they will be constructed
- What constituents will be analyzed.

More detailed information may be required for your specific proposal. Please contact us early in the process to determine what requirements will be needed to ensure you are able to submit a complete application.

3.6 How will the phosphogypsum be handled at the study site?

Your petition should include the details of how the phosphogypsum will be handled from the point of release at the stack to your site, during the study, and how any remaining materials will be removed from the site and returned to the stack. You should describe procedures to prevent the unauthorized access to or use of materials at the site. What are the controls to ensure you do not receive excess materials? How will the excess material be returned?

3.7 What are the expected benefits of the proposed use?

As described in section 2.4, your petition should include a discussion of the effectiveness of proposed use relative to leaving the phosphogypsum in the stack. Your proposed use should be a legitimate use with real benefits and not intended merely as a disposal option. Attention to the benefit of the use is consistent with national and international approaches to radiation protection: "No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes." *1990 Recommendations of the ICRP*

4.0 Risk Assessment

4.1 What is a risk assessment?

A risk assessment is a scientific analysis that examines the ways that your proposed use could expose people and the environment to phosphogypsum radiation, how great the exposure would be, and what health effects can be expected. The risk assessment should be designed to confirm that the potential radiological risk from the proposed alternative use is:

- At least as protective of public health, in both the short term and the long term, as disposal of phosphogypsum in a stack or mine (40 CFR 61.206(c)).
- Is an appropriate level of risk, acceptable and consistent with the NESHAP program and the Clean Air Act.

Most radiologic risk assessments include the inhalation or air exposure pathway. Air and water concentrations of radionuclides and exposure conditions are used to calculate radionuclide intakes from which one can estimate excess cancer risk. (Federal Guidance Report No. 13 lists risk per unit intake for ingestion and inhalation of radionuclides). Air concentrations used in risk assessments can be estimated from models, ambient monitors, or a combination of the two. Likewise, water concentrations can be estimated by models, water monitoring, or a combination of both. A preliminary risk assessment may assume default exposure conditions and that lifetime exposure occurs. Further refinement of the risk assessment can be made as necessary.

The radionuclides, uranium and radium-226, are present in phosphogypsum and can become airborne. Once in the air, people and animals can breathe them and they can settle out onto ponds and agricultural areas. Radon-222, a decay product of radium-226, is a gas and so may become airborne by diffusing into the air.

To the extent the phosphogypsum is land applied or will remain in place following the test, the risk assessment must examine other potential pathways of exposure, in particular with respect to groundwater and surface water. Consideration of multiple pathways, particularly pathways associated with groundwater, are consistent with our review of alternative uses as found in the 1992 rulemaking on phosphogypsum. To model these additional pathways, it will be necessary for you to obtain some site-specific information (depending on your individual application), such as:

- Soil/landfill properties (e.g., soil types, densities, distribution coefficients)
- Water table properties (e.g, depth, hydraulic gradient)
- Meteorological data (e.g., average rainfall)
- Land use scenario data for the region.

The risk assessment is a key part of your petition and must be submitted with your petition in order to be determined complete. You should consider conducting a screening level

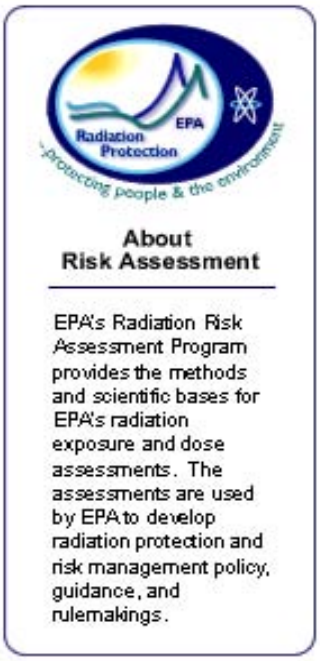
assessment first to determine the overall magnitude of risk posed by your proposed use. If the initial risk appears high, you may want to refine your idea to reduce the risk and then conduct a refined assessment to better understand risk factors and assumptions that influence the outcome of the analysis. See section 5.0 for more discussion of the EPA models that are available for estimating cancer risks from exposure to radionuclides.

Please contact us if you have additional questions on how to conduct a risk assessment for your petition. The following materials provide a good starting point for conducting a risk assessment:

Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A)
USEPA, Office of Emergency and Remedial Response, Washington, DC 20460,
December, 1989
EPA/540/1-89/002

Exposure Factors Handbook, Volume 1, General Factors
USEPA, Office of Research and Development, Washington, DC 20460
August, 1997
EPA/600/P-95/002Fa

Guidelines for Exposure Assessment
Published on May 29, 1992 in the *Federal Register* at 57 FR 22888-22938



4.2 How do the results of the risk assessment affect the decision on approval?

The risk assessment must demonstrate that the proposed other use will not cause a threat to the public or environment greater than if the phosphogypsum were left in the stack. This means that the risk assessment must show that the chance of developing a fatal cancer in people who are exposed to phosphogypsum as a result of the use for which you are applying must not increase more that three in ten thousand (3×10^{-4}). To put this number in perspective and allow you to see how little increase in risk is permitted, the risk in the United States of developing a fatal cancer is about one in four.

5.0 Risk Models

5.1 What EPA models are available?

> Risk models are a series of mathematical equations combining the impact of many different factors that determine the health effects of your proposed use. For example, if your proposed use involves making a product that goes in the ground, the potential for the phosphogypsum to affect the health of people near it will depend on how dry or wet the soil is, how close it will be to drinking wells, whether there are people living near where you propose to use it, etc. A risk model contains equations to account for all these factors.

EPA has made available multiple models for estimating cancer risks from exposure to radionuclides. The models are unique because they include not only fate and transport of radionuclides released to air and other media, but also estimate dose and risk. The first question to ask when selecting a computer model for your assessment is which exposure pathways do you need to simulate. (If you are unsure, please contact EPA.)

- For air pathway only simulations, the COMPLYR and CAP-88 models are available.
- EPACMTP is used to simulate the impact of the release of constituents present in waste that is managed in land disposal units.

COMPLYR is an atmospheric screening model for assessing dose from radioactive air emissions. COMPLYR calculates the effective dose equivalent (ede) from radionuclides released from stacks and vents. Atmospheric concentrations are estimated using a Gaussian plume model and equations that account for building wake effects. For more information on this model, go to the EPA radiation website at: http://www.epa.gov/radiation/assessment/comply.html.

The CAP-88 (which stands for Clean Air Act Assessment Package-1988) computer model is a set of computer programs, databases and associated utility programs for estimation of dose and risk from radionuclide emissions to air. The CAP88-PC software, released in 1992, allows the user to complete CAP-88 dose and risk assessment calculations in a personal computer environment. For more information on this model, go to the EPA radiation website at: http://www.epa.gov/radiation/assessment/CAP88/index.html.

The EPA CMTP (Composite Model for Leachate Migration with Transformation Products) is a subsurface fate and transport model used to establish concentrations of constituents in wastes managed in land-based units. EPACMTP can simulate the subsurface migration of leachate from four different types of waste management units: landfills, waste piles, surface impoundments, or land application units.

Guidance on models for estimating risks from other constituents is also available from EPA in the Air Toxics Risk Assessment Reference Library at: http://www.epa.gov/ttn/fera/risk_atra_main.html.

5.2 Which models should I use and how can I obtain them?

As a first step, review the EPA models described in section 5.1. Also, please feel free to contact us for help because we may be able to provide additional guidance on selecting appropriate models.

If you decide to use a different model, you must send us an electronic copy of the model, a user's manual, and verification and validation information, at a minimum. We will review the information and let you know if it is appropriate for conducting a risk assessment.

6.0 Other Requirements

6.1 Are there any other EPA requirements than those related to the petition?

As described in section 2.4 of this document and consistent with 40 CFR 61.106(e), if we decide to grant a request that approves distribution and/or use of phosphogypsum for a specified purpose, we may decide to impose additional terms or conditions governing such distribution or use. In some cases, we may require you to take special precautions. For example, if you are proposing to use phosphogypsum in a way that would bring it into contact with the surface of the ground, such as using it for a road base, we will probably require you to establish a groundwater monitoring program. In other cases, we might require use of a synthetic geomembrane as part of a landfill cap design.

6.2 If I meet EPA requirements, do I have to consider other Federal and/or state and local requirements?

As a matter of practice, we keep the affected EPA Regional Office, State Agency, and other relevant jurisdictions informed of activities related to your petition. Before you send in your petition, it would be wise to talk to the other regulators to ensure that you can proceed. If you aren't sure whom to contact, we will be able to help you.

Note that our approval of your petition does not supersede any other Federal (e.g., OSHA), local, or state requirements. For example, as described in section 3.0 of this document, a project that would affect the marine environment requires your compliance with the MPRSA, which prohibits the dumping of material into the ocean that would unreasonably degrade or endanger human health or the marine environment. Ocean dumping cannot occur unless a permit is issued under the MPRSA.

6.3 What recordkeeping requirements must I meet?

The end-user of the phosphogypsum must retain records that conform to the requirements of 40 CFR 61.209(c) for at least 5 years from the date of use of the phosphogypsum. For example, in the case of a petition to use the phosphogypsum as a landfill cover, the end-user would be the landfill facility. Your petition must ensure that the records requirement shall be met.

The records must include the following information:

- The name and address of the person in charge of the activity involving use of phosphogypsum
- A description of each use of phosphogypsum, including the handling and processing that the phosphogypsum will undergo

- The location of each site where each use of phosphogypsum occurred, including the suite and/or building number, street, city, county, state, and zip code
- The mailing address of each facility using phosphogypsum, if different from that described above
- The date of each use of phosphogypsum
- The quantity of phosphogypsum used
- The certified average concentration of radium-226 for the phosphogypsum which was used
- A description of all measures taken to prevent the uncontrolled release of phosphogypsum into the environment
- A description of the disposition of any unused phosphogypsum.

In appropriate circumstances, we may also decide to waive or modify the recordkeeping requirements established by 40 CFR 61.209(c).

6.4 What are the certification requirements and how do I meet them?

As described in section 3.2 of this document, 40 CFR 61.207 establishes radium-226 sampling and measurement procedures to characterize the phosphogypsum. The certification requirements in 40 CFR 61.208 are designed to ensure the information on radium-226 concentration is documented and available at all times, whenever phosphogypsum is removed from a stack for "distribution in commerce" under 40 CFR 61.206. Prior to removal and using the procedures defined in 40 CFR 61.207, the owner or operator of a phosphogypsum stack must measure the average radium-226 concentration at the location in the stack from which phosphogypsum will be removed. Then, under 40 CFR 61.208, the owner or operator must prepare a certificate document for each quantity of phosphogypsum which is distributed in commerce that includes:

- The name and address of the owner or operator
- The name and address of the purchaser or recipient of the phosphogypsum
- The quantity (in pounds) of phosphogypsum sold or transferred
- The date of sale or transfer
- A description of the intended end-use for the phosphogypsum
- The average radium-226 concentration, in pCi/g, of the phosphogypsum, as determined according to 40 CFR 61.207
- The signature of the person who prepared the certification.

Each distributor, retailer, or reseller who purchases or receives phosphogypsum for subsequent resale or transfer must prepare a certification document for each quantity of phosphogypsum that is resold or transferred that includes:

- The name and address of the distributor, retailer, or reseller

- The name and address of the purchaser or recipient of the phosphogypsum
- The quantity (in pounds) of phosphogypsum resold or transferred
- The date of resale or transfer
- A description of the intended end-use for the phosphogypsum
- A copy of each certification document which accompanied the phosphogypsum at the time it was purchased or received by the distributor, retailer, or reseller
- The signature of the person who prepared the certification.

Therefore, all phosphogypsum distributed in commerce by the owner or operator of a phosphogypsum stack, or by a distributor, retailer, or reseller, or purchased by the end-user must be accompanied at all times by certification documents that conform to 40 CFR 61.208. While the particular use described in your petition may not be described as "commerce" in a strict sense, there is an end-user, and the petition must address this requirement.

6.5 What post-approval requirements must I meet?

Section 6.4, above, describes the ongoing recordkeeping requirements as specified in subpart R. Additional requirements may be added as approval conditions. Similarly, we may add reporting requirements to your approval. In any case, we may contact you from time to time for an update.

"Other uses" are approved as long as nothing in the petition changes. If some piece of information changes, you must notify us. You probably won't be required to do any additional work unless the change is in one of the factors that was considered in the risk analysis. When factors that affect the risk of the use change, you may have to redo part or all of the risk analysis. Factors that could affect the risk analysis results include a decision to use phosphogypsum from a different stack or supplier than indicated in your approved petition. Also, if you submit a petition to manufacture a specific product and later realize it can be used for another purpose, you must complete and submit a new petition containing a new use-specific risk analysis.

Once approved, your petition can be revoked if you violate the approved process. For example, if you say you are going to be making your product in State A, then shipping it to State B for testing, and we discover you have sent it to State C for testing, we may revoke your approval. It is possible that we could involve our Office of Enforcement and Compliance Assurance for further penalties. It is much easier to contact us beforehand and discuss any needed changes to your approved petition.

Unless specified in your approval, there is no "official" closeout to your project. However, we request that you send us a courtesy letter informing us when you complete your study and closeout the site so that our records are complete. Your petition must include information regarding final disposition of the test site and phosphogypsum used and your approval will confirm the final requirements.

Appendix A

40 CFR 61.200 - 210

PART 61-National Emission Standards for Hazardous Air Pollutants
Subpart R: National Emission Standards for Radon Emissions from Phosphogypsum Stacks

§ 61.200 Designation of facilities.

The provisions of this subpart apply to each owner or operator of a phosphogypsum stack, and to each person who owns, sells, distributes, or otherwise uses any quantity of phosphogypsum which is produced as a result of wet acid phosphorus production or is removed from any existing phosphogypsum stack.

§ 61.201 Definitions.

As used in this subpart, all terms not defined here have the meaning given them in the Clean Air Act or subpart A of part 61. The following terms shall have the following specific meanings:
(a) *Inactive stack* means a stack to which no further routine additions of phosphogypsum will be made and which is no longer used for water management associated with the production of phosphogypsum. If a stack has not been used for either purpose for two years, it is presumed to be inactive.
(b) *Phosphogypsum* is the solid waste byproduct which results from the process of wet acid phosphorus production.
(c) *Phosphogypsum stacks* or *stacks* are piles of waste resulting from wet acid phosphorus production, including phosphate mines or other sites that are used for the disposal of phosphogypsum.

§ 61.202 Standard.

Each person who generates phosphogypsum shall place all phosphogypsum in stacks. Phosphogypsum may be removed from a phosphogypsum stack only as expressly provided by this subpart. After a phosphogypsum stack has become an inactive stack, the owner or operator shall assure that the stack does not emit more than 20 pCi/(m 2-sec) (1.9 pCi/(ft 2-sec)) of radon-222 into the air.

§ 61.203 Radon monitoring and compliance procedures.

(a) Within sixty days following the date on which a stack becomes an inactive stack, or within ninety days after the date on which this subpart first took effect if a stack was already inactive on that date, each owner or operator of an inactive phosphogypsum stack shall test the stack for radon-222 flux in accordance with the procedures described in 40 CFR part 61, appendix B, Method 115. EPA shall be notified at least 30 days prior to each such emissions test so that EPA may, at its option, observe the test. If meteorological conditions are such that a test cannot be properly conducted, then the owner or operator shall notify EPA and test as soon as conditions permit.
(b)(1) Within ninety days after the testing is required, the owner or operator shall provide EPA with a report detailing the actions taken and the results of the radon-222 flux testing. Each report shall also include the following information:

(i) The name and location of the facility;
(ii) A list of the stacks at the facility including the size and dimensions of each stack;
(iii) The name of the person responsible for the operation of the facility and the name of the person preparing the report (if different);
(iv) A description of the control measures taken to decrease the radon flux from the source and any actions taken to insure the long term effectiveness of the control measures; and
(v) The results of the testing conducted, including the results of each measurement.
(2) Each report shall be signed and dated by a corporate officer in charge of the facility and contain the following declaration immediately above the signature line: "I certify under penalty of law that I have personally examined and am familiar with the information submitted herein and based on may inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment. See, 18 U.S.C. 1001."
(c) If the owner or operator of an inactive stack chooses to conduct measurements over a one year period as permitted by Method 115 in appendix B to part 61, within ninety days after the testing commences the owner or operator shall provide EPA with an initial report, including the results of the first measurement period and a schedule for all subsequent measurements. An additional report containing all the information in §61.203(b) shall be submitted within ninety days after completion of the final measurements.
(d) If at any point an owner or operator of a stack once again uses an inactive stack for the disposal of phosphogypsum or for water management, the stack ceases to be in inactive status and the owner or operator must notify EPA in writing within 45 days. When the owner or operator ceases to use the stack for disposal of phosphogypsum or water management, the stack will once again become inactive and the owner or operator must satisfy again all testing and reporting requirements for inactive stacks.
(e) If an owner or operator removes phosphogypsum from an inactive stack, the owner shall test the stack in accordance with the procedures described in 40 CFR part 61, appendix B, Method 115. The stack shall be tested within ninety days of the date that the owner or operator first removes phosphogypsum from the stack, and the test shall be repeated at least once during each calendar year that the owner or operator removes additional phosphogypsum from the stack. EPA shall be notified at least 30 days prior to an emissions test so that EPA may, at its option, observe the test. If meteorological conditions are such that a test cannot be properly conducted, then the owner shall notify EPA and test as soon as conditions permit. Within ninety days after completion of a test, the owner or operator shall provide EPA with a report detailing the actions taken and the results of the radon-222 flux testing. Each such report shall include all of the information specified by §61.203(b).

§ 61.204 Distribution and use of phosphogypsum for outdoor agricultural purposes.
Phosphogypsum may be lawfully removed from a stack and distributed in commerce for use in outdoor agricultural research and development and agricultural field use if each of the following requirements is satisfied:

(a) The owner or operator of the stack from which the phosphogypsum is removed shall determine annually the average radium-226 concentration at the location in the stack from which the phosphogypsum will be removed, as provided by §61.207.
(b) The average radium-226 concentration at the location in the stack from which the phosphogypsum will be removed, as determined pursuant to §61.207, shall not exceed 10 pCi/g (4500 pCi/lb).
(c) All phosphogypsum distributed in commerce for use pursuant to this section by the owner or operator of a phosphogypsum stack shall be accompanied by a certification document which conforms to the requirements of §61.208(a).
(d) Each distributor, retailer, or reseller who distributes phosphogypsum for use pursuant to this section shall prepare certification documents which conform to the requirements of §61.208(b).
(e) Use of phosphogypsum for indoor research and development in a laboratory must comply with §61.205.

§ 61.205 Distribution and use of phosphogypsum for indoor research and development.
(a) Phosphogypsum may be lawfully removed from a stack and distributed in commerce for use in indoor research and development activities, provided that it is accompanied at all times by certification documents which conform to the requirements of §61.208. In addition, before distributing phosphogypsum to any person for use in indoor research and development activities, the owner or operator of a phosphogypsum stack shall obtain from that person written confirmation that the research facility will comply with all of the limitations set forth in paragraph (b) of this section.
(b) Any person who purchases and uses phosphogypsum for indoor research and development purposes shall comply with all of the following limitations. Any use of phosphogypsum for indoor research and development purposes not consistent with the limitations set forth in this section shall be construed as unauthorized distribution of phosphogypsum.
(1) Each quantity of phosphogypsum purchased by a facility for a particular research and development activity shall be accompanied by certification documents which conform to the requirements of §61.208.
(2) No facility shall purchase or possess more than 3182 kg (7,000 lb) of phosphogypsum for a particular indoor research and development activity. The total quantity of all phosphogypsum at a facility, as determined by summing the individual quantities purchased or possessed for each individual research and development activity conducted by that facility, may exceed 3182 kg (7,000 lb), provided that no single room in which research and development activities are conducted shall contain more than 3182 kg (7,000 lb).
(3) Containers of phosphogypsum used in indoor research and development activities shall be labeled with the following warning: Caution: Phosphogypsum Contains Elevated Levels of Naturally Occurring Radioactivity.
(4) For each indoor research and development activity in which phosphogypsum is used, the facility shall maintain records which conform to the requirements of §61.209(c).
(5) Indoor research and development activities must be performed in a controlled laboratory setting which the general public cannot enter except on an infrequent basis for tours of the

facility. Uses of phosphogypsum for outdoor agricultural research and development and agricultural field use must comply with §61.204.
(c) Phosphogypsum not intended for distribution in commerce may be lawfully removed from a stack by an owner or operator to perform laboratory analyses required by this subpart or any other quality control or quality assurance analyses associated with wet acid phosphorus production.

§ 61.206 Distribution and use of phosphogypsum for other purposes.
(a) Phosphogypsum may not be lawfully removed from a stack and distributed or used for any purpose not expressly specified in §61.204 or §61.205 without prior EPA approval.
(b) A request that EPA approve distribution and/or use of phosphogypsum for any other purpose must be submitted in writing and must contain the following information:
(1) The name and address of the person(s) making the request.
(2) A description of the proposed use, including any handling and processing that the phosphogypsum will undergo.
(3) The location of each facility, including suite and/or building number, street, city, county, state, and zip code, where any use, handling, or processing of the phosphogypsum will take place.
(4) The mailing address of each facility where any use, handling, or processing of the phosphogypsum will take place, if different from paragraph (b)(3) of this section.
(5) The quantity of phosphogypsum to be used by each facility.
(6) The average concentration of radium-226 in the phosphogypsum to be used.
(7) A description of any measures which will be taken to prevent the uncontrolled release of phosphogypsum into the environment.
(8) An estimate of the maximum individual risk, risk distribution, and incidence associated with the proposed use, including the ultimate disposition of the phosphogypsum or any product in which the phosphogypsum is incorporated.
(9) A description of the intended disposition of any unused phosphogypsum.
(10) Each request shall be signed and dated by a corporate officer or public official in charge of the facility.
(c) The Assistant Administrator for Air and Radiation may decide to grant a request that EPA approve distribution and/or use of phosphogypsum if he determines that the proposed distribution and/or use is at lease as protective of public health, in both the short term and the long term, as disposal of phosphogypsum in a stack or a mine.
(d) If the Assistant Administrator for Air and Radiation decides to grant a request that EPA approve distribution and/or use of phosphogypsum for a specified purpose, each of the following requirements shall be satisfied:
(1) The owner or operator of the stack from which the phosphogypsum is removed shall determine annually the average radium-226 concentration at the location in the stack from which the phosphogypsum will be removed, as provided by §61.207.
(2) All phosphogypsum distributed in commerce by the owner or operator of a phosphogypsum stack, or by a distributor, retailer, or reseller, or purchased by the end-user, shall be accompanied at all times by certification documents which conform to the requirements §61.208.

(3) The end-user of the phosphogypsum shall maintain records which conform to the requirements of §61.209(c).
(e) If the Assistant Administrator for Air and Radiation decides to grant a request that EPA approve distribution and/or use of phosphogypsum for a specified purpose, the Assistant Administrator may decide to impose additional terms or conditions governing such distribution or use. In appropriate circumstances, the Assistant Administrator may also decide to waive or modify the recordkeeping requirements established by §1.209(c).

§ 61.207 Radium-226 sampling and measurement procedures.
(a) Before removing phosphogypsum from a stack for distribution in commerce pursuant to §61.204, or §61.206, the owner or operator of a phosphogypsum stack shall measure the average radium-226 concentration at the location in the stack from which phosphogypsum will be removed. Measurements shall be performed for each such location prior to the initial distribution in commerce of phosphogypsum removed from that location and at least once during each calendar year while distribution of phosphogypsum removed from the location continues.
(1) A minimum of 30 phosphogypsum samples shall be taken at regularly spaced intervals across the surface of the location on the stack from which the phosphogypsum will be removed. Let $n1$ represent the number of samples taken.
(2) Measure the radium-226 concentration of each of the $n1$ samples in accordance with the analytical procedures described in 40 CFR part 61, appendix B, Method 114.
(3) Calculate the mean, x 1, and the standard deviation, $s1$, of the $n1$ radium-226 concentrations:

$$\overline{x_1} = \frac{\sum_{i=1}^{n_1} x_i}{n_1},$$

$$s_1 = \sqrt{\frac{\sum_{i=1}^{n_1} \left(x_i - \overline{x_1}\right)^2}{n_1 - 1}},$$

Where x 1 and $s1$ are expressed in pCi/g.
(4) Calculate the 95th percentile for the distribution, x *, using the following equation:

$$\overline{x}^* = \overline{x_1} + 1.64\left(\frac{s_1}{\sqrt{n_1}}\right),$$

Where x * is expressed in pCi/g.

(5) If the purpose for removing phosphogypsum from a stack is for distribution to commerce pursuant to §61.206, the owner or operator of a phosphogypsum stack shall report the mean, standard deviation, 95th percentile and sample size. If the purpose for removing phosphogypsum from a stack is for distribution to commerce pursuant to §61.204, the additional sampling procedures set forth in paragraphs (b) and (c) of this section shall apply.
(b) Based on the values for x 1 and x * calculated in paragraphs (a)(3) and (4) of this section, determine which of the following conditions will be met:
(1) If x 1 < 10 pCi/g and x * ≤= 10 pCi/g; phosphogypsum may be removed from this area of the stack for distribution in commerce pursuant to §61.204.
(2) If x 1, < 10 pCi/g and x * > 10 pCi/g, the owner or operator may elect to follow the procedures for further sampling set forth in paragraph (c) of this section:
(3) If x 1 ≥= 10 pCi/g; phosphogypsum shall not be removed from this area of the stack for distribution in commerce pursuant to §61.204.
(c) If the owner or operator elects to conduct further sampling to determine if phosphogypsum can be removed from this area of the stack, the following procedure shall apply. The objective of the following procedure is to demonstrate, with a 95% probability, that the phosphogypsum from this area of the stack has a radium-226 concentration no greater than 10 pCi/g. The procedure is iterative, the sample size may have to be increased more than one time; otherwise the phosphogypsum cannot be removed from this area of the stack for distribution to commerce pursuant to §61.204.
(1)(i) Solve the following equation for the total number of samples required:

$$n_2 = \left(\frac{1.64 s_1}{10 - \overline{x}_1} \right)^2 .$$

(ii) The sample size n2 shall be rounded upwards to the next whole number. The number of additional samples needed is nA = n2 - -n1.
(2) Obtain the necessary number of additional samples, nA, which shall also be taken at regularly spaced intervals across the surface of the location on the stack from which phosphogypsum will be removed.
(3) Measure the radium-226 concentration of each of the nA additional samples in accordance with the analytical procedures described in 40 CFR part 61, appendix B, Method 114.
(4) Recalculate the mean and standard deviation of the entire set of n2 radium-226 concentrations by joining this set of nA concentrations with the n1 concentrations previously measured. Use the formulas in paragraph (a)(3) of this section, substituting the entire set of n2 samples in place of the n1 samples called for in paragraph (a)(3) of this section, thereby determining the mean, x 2, and standard deviation, s2, for the entire set of n2 concentrations.
(5) Repeat the procedure described in paragraph (a)(4) of this section, substituting the recalculated mean, x 2, for x 1, the recalculated standard deviation, s2, for s1, and total sample size, n2, for n1.

(6) Repeat the procedure described in paragraph (b) of this section, substituting the recalculated mean, x 2 for x 1.

§ 61.208 Certification requirements.

(a)(1) The owner or operator of a stack from which phosphogypsum will be removed and distributed in commerce pursuant to §61.204, §61.205, or §61.206 shall prepare a certification document for each quantity of phosphogypsum which is distributed in commerce which includes:
(i) The name and address of the owner or operator;
(ii) The name and address of the purchaser or recipient of the phosphogypsum;
(iii) The quantity of phosphogypsum, in kilograms or pounds sold or transferred;
(iv) The date of sale or transfer;
(v) A description of the intended end-use for the phosphogypsum;
(vi) The average radium-226 concentration, in pCi/g (pCi/lb), of the phosphogypsum, as determined pursuant to §61.207; and
(vii) The signature of the person who prepared the certification.
(2) The owner or operator shall retain the certification document for five years from the date of sale or transfer, and shall produce the document for inspection upon request by the Administrator, or his authorized representative. The owner or operator shall also provide a copy of the certification document to the purchaser or recipient.
(b)(1) Each distributor, retailer, or reseller who purchases or receives phosphogypsum for subsequent resale or transfer shall prepare a certification document for each quantity of phosphogypsum which is resold or transferred which includes:
(i) The name and address of the distributor, retailer, or reseller;
(ii) The name and address of the purchaser or recipient of the phosphogypsum;
(iii) The quantity (in pounds) of phosphogypsum resold or transferred;
(iv) The date of resale or transfer;
(v) A description of the intended end-use for the phosphogypsum;
(vi) A copy of each certification document which accompanied the phosphogypsum at the time it was purchased or received by the distributor, retailer, or reseller; and
(vii) The signature of the person who prepared the certification.
(2) The distributor, retailer, or reseller shall retain the certification document for five years from the date of resale or transfer, and shall produce the document for inspection upon request by the Administrator, or his authorized representative. For every resale or transfer of phosphogypsum to a person other than an agricultural end-user, the distributor, retailer, or reseller shall also provide a copy of the certification document to the purchaser or transferee.

§ 61.209 Required records.

(a) Each owner or operator of a phosphogypsum stack must maintain records for each stack documenting the procedure used to verify compliance with the flux standard in §61.202, including all measurements, calculations, and analytical methods on which input parameters were based. The required documentation shall be sufficient to allow an independent auditor to verify the correctness of the determination made concerning compliance of the stack with flux standard.

(b) Each owner or operator of a phosphogypsum stack must maintain records documenting the procedure used to determine average radium-226 concentration pursuant to §61.207, including all measurements, calculations, and analytical methods on which input parameters were based. The required documentation shall be sufficient to allow an independent auditor to verify the accuracy of the radium-226 concentration.
(c) Each facility which uses phosphogypsum pursuant to §61.205 or §61.206 shall prepare records which include the following information:
(1) The name and address of the person in charge of the activity involving use of phosphogypsum.
(2) A description of each use of phosphogypsum, including the handling and processing that the phosphogypsum underwent.
(3) The location of each site where each use of phosphogypsum occurred, including the suite and/or building number, street, city, county, state, and zip code.
(4) The mailing address of each facility using phosphogypsum, if different from paragraph (c)(3) of this section.
(5) The date of each use of phosphogypsum.
(6) The quantity of phosphogypsum used.
(7) The certified average concentration of radium-226 for the phosphogypsum which was used.
(8) A description of all measures taken to prevent the uncontrolled release of phosphogypsum into the environment.
(9) A description of the disposition of any unused phosphogypsum.
(d) These records shall be retained by the facility for at least five years from the date of use of the phosphogypsum and shall be produced for inspection upon request by the Administrator, or his authorized representative.

§ 61.210 Exemption from the reporting and testing requirements of 40 CFR 61.10.
All facilities designated under this subpart are exempt from the reporting requirements of 40 CFR 61.10.

Appendix B

Petition Completeness Checklist

PETITION COMPLETENESS CHECKLIST

Does your petition contain the following information?

- The name and address of the person(s) making the request.

- A description of the proposed use(s), including the following:
  - ♦ A detailed description of the small-scale study (field test, control test, QA/QC plans, illustrative diagrams/pictures)
  - ♦ How the phosphogypsum will be handled or processed during each stage of the study, including closure (if applicable)
  - ♦ Goals of the study and how performance will be measured
  - ♦ Characteristics of the phosphogypsum to be used (radium-226 concentration, as defined below, as well as information on other characteristics of the waste such as toxic or hazardous constituents and mobility of constituents, presence of hazardous air pollutants)

☐ The location of each facility, including suite and/or building number, street, city, county, state, and zip code, where any use, handling, or processing of the phosphogypsum will take place. If the mailing address is different, provide it too.

☐ The quantity of phosphogypsum to be used by each facility.

☐ The average concentration of radium-226 in the phosphogypsum to be used. This information may be available from the owner of the stack. The sampling must have been done within the past 12 months according to the procedures in 40 CFR 61.207. Include a copy of the necessary 40 CFR 61.208 certification with your petition.

☐ A description of any measures which will be taken to prevent the uncontrolled release of radium 226, radon, or other hazardous constituents into the environment. This includes description of any monitoring plans for air and water pathways and worker exposure, leak prevention programs, and QA/QC measures.

☐ An estimate of the maximum individual risk and incidence associated with the proposed use, including the ultimate disposition of the phosphogypsum or any product in which the phosphogypsum is incorporated. Include a copy of the risk assessment procedures, assumptions, and results. If you use a non-EPA model, provide a copy of the model and all needed documentation to understand and use the model.

☐ How the phosphogypsum will be handled at the study site, including procedures to prevent unauthorized access and handling of excess materials.

☐ Description of the effectiveness and benefit of the proposed use.

☐ Description of any other Federal, state, and/or local requirements affected by the proposed use and how they will be satisfied.

☐ Description of any recordkeeping and reporting procedures, including the certification requirements, and how they will be met.

☐ Each request shall be signed and dated by a corporate officer or public official in charge of the facility.